(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Directors for Science and for Regulations Policy, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the PHS Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing under the provisions of part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of §16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner of Food and Drugs (Commissioner).

(2) The Director and Deputy Director, CFSAN.

(3) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER); the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER, the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors for Science and for Regulations Policy, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

(d) These officials may not further redelegate this authority.

§ 5.29 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date in §201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs:

(1)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(2)(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter requesting in vitro test modifications under §331.29 of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in §§211.132, 700.25, or 800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); and the Director of Regulations and Policy, CFSAN.

(3) The Director and the Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(d) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter requesting exemption from the general pregnancy-nursing warning for over-the-counter (OTC) drugs required under §201.63 of this chapter, requesting exemption from a general overdose warning required under §330.1(g) of this chapter, and requesting exemption from OTC drug administrative procedures under §330.10 of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e)(1) The following officials are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Cosmetics and Colors, CFSAN.

(iv) The Director, Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN.

(v) The Director, Office of Premarket Approval, CFSAN.

(vi) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(vii) The Director, Office of Seafood, CFSAN.

(viii) The Director, Office of Field Programs, CFSAN.

(2) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(3) The Director and Deputy Directors, CBER, are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(4) The Director, the Deputy Director, and the Associate Director for Regulatory Policy, CDER, are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(5) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(f)(1) The Director and Deputy Directors, CBER, are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter on drug and biological product matters in program areas where they have been delegated final approval authority in the following sections of this chapter:

(i) Section 5.203 *Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products*;

(ii) Section 5.204 *Notification of release for distribution of biological products*;

(iii) Section 5.101 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iv) Section 5.103 *Approval of new drug applications and their supplements*.

(v) Section 5.105 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements*.

(vi) Section 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment*.

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug product matters in program areas where they have been delegated final approval authority in the following sections of this chapter:

(i) Section 5.100 *Issuance of notices implementing the provisions of the Drug Amendments of 1962*;

(ii) Section 5.101 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iii) Section 5.103 *Approval of new drug applications and their supplements*.

(iv) Section 5.105 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements*.

(v) Section 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment*.

(3) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, except for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(4) The Directors and Deputy Directors of OBRR, OVRR, and OTRR, CBER, for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(5) For drugs assigned to their organization, the following officials are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new drug application who request approval to ship in interstate commerce, in accordance with § 2.125(j) of this chapter, an investigational new drug for human use containing a chlorofluorocarbon.

(i) The Director and Deputy Directors, CBER.

(ii) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(6) The Director and Deputy Director, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new animal drug application who request approval to ship in interstate commerce, in accordance with § 21.125(j) of this chapter, an investigational new animal drug for animal use containing a chlorofluorocarbon.

(7) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product.

(8) The Director and Deputy Director, CVM, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter concerning actions they are authorized to take under § 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment*.

(g) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director, Office of Compliance, CDRH, are authorized to grant or deny citizen petitions submitted under §§ 10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

(h) These officials may not further redelegate this authority.

§ 5.30 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.

(a) Each Center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that Center's management to serve temporarily as voting members on another advisory committee under that Center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees, if such voting members are serving on an advisory committee managed by another Center, has not been redelegated. This authority will continue to be exercised by the Commissioner of Food and Drugs (Commissioner) or the Senior Associate Commissioner, Office of the Commissioner.

(b) Each Center director is authorized, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special Government employees without substantial interest to serve as consultants to advisory committees or in any other capacity within the Centers except as advisory committee members.

(c) These officials may not further redelegate this authority.

§ 5.31 Enforcement activities.

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA–200A, Identification Record, and Form FDA–200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 372 (e) (5)); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461), the Federal Caustic Poison Act (44 Stat. 140b; see also Public Law 86–613, section 19, formerly section 18), the Import Milk Act (21 U.S.C. 141–149), the Filled Milk Act (21 U.S.C. 61–64), and sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264).

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner of Food and Drugs (Commissioner) to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA–200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act (21 U.S.C. 372 (e)(1)–(e)(5)):

(i) Carry firearms;

(ii) Serve and execute search warrants and arrest warrants;

(iii) Execute seizure by process issued under libel under section 304 of the act (21 U.S.C. 334);

(iv) Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(v) Make, prior to the institution of libel proceedings under section 304(a)(2) of the act (21 U.S.C. 334(a)(2)), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable